1 IN THE CIRCUIT COURT OF OHIO COUNTY
2 WHEELING, WEST VIRGINIA
3
4 IN RE:
5 TOBACCO LITIGATION CASE NO. 00-C-6000
6 MEDICAL MONITORING CASES
7
8 * * *
9
10 JURY TRIAL
11
12 Whereupon the above-entitled matter came on for
13 hearing before the Honorable Arthur M. Recht at the
14 Ohio County Courthouse, Wheeling, West Virginia, and
15 the proceedings are as follows.
16
17
18
19 * * *
20
VOLUME 24-A
21
November 7, 2001
22
8:30 a.m.
23
24 * * *

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I N D E X

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Donald B. Louria, M.D.	
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(There are other counsel representing interested parties also present in the courtroom gallery.)

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Wednesday Morning Session
November 7, 2001
8:30 a.m.
-- -- --
P R O C E E D I N G S
-- -- --

(In open court with a jury present.)

THE COURT: Be seated, please. Good morning, everybody.

All right. Ready to do whatever you are going to do?

MR. FURR: Yes, sir.

THE COURT: All right.

MR. WOODSIDE: Are we starting -- I just want to make sure, we are going to do exhibits later?

Your Honor, the defendants will call Dr. Donald Louria.

THE COURT: All right. Just step forward, please, sir. The young lady will administer the oath to you.

Just have a seat over here, please, sir. Watch your step there. That microphone is now working.

MR. WOODSIDE: Good morning, ladies and gentlemen.

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-- -- --

DONALD B. LOURIA, M.D.,
being first duly sworn by the Clerk, testifies and
says as follows:

-- -- --

DIRECT EXAMINATION

BY MR. WOODSIDE:

Q. Dr. Louria, would you please state your name for the record.

A. Donald B. Louria.

Q. And your birth place, sir?

A. New York City.

Q. And your age?

A. Seventy-three.

Q. Okay. And sir, where do you reside?

A. In New Jersey.

Q. And you are a physician; correct?

A. I am.

Q. And would you please tell the ladies and gentlemen your professional address and your current position?

A. I'm Chairman Emeritus of the Department of Preventive Medicine at the New Jersey Medical School in Newark, New Jersey.

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Q. And are you also a professor of preventative medicine?
A. I'm a professor of preventative medicine and a professor of medicine.
Q. And sir, do you still work full-time?
A. I'm full-time.
Q. And are you married, sir?
A. Yes.
Q. And do you have any children?
A. Three.
Q. Okay. Now, let me start back and go through your education in some detail. Where did you go to college?
A. Harvard.
Q. And when did you graduate and what was your major?
A. Graduated in 1949, my major was social relations.
Q. And did you receive any honors at Harvard?
A. I graduated with honors.
Q. Okay. And thereafter, did you go to medical school?
A. I did.
Q. And where did you go to medical school?

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A. Harvard.
Q. And when did you graduate?
A. 1953.
Q. And did you graduate with honors from Harvard Medical School?
A. I did.
Q. Thereafter, did you take any internship and residency?
A. I did. At Cornell University Medical School. That's New York Hospital, New York City.
Q. And in what field did you take your internship and residency?
A. Internal medicine.
Q. All right. And as I understand it, you did that for two years?
A. I did that for two years, that's right.
Q. And thereafter, did you go into the Public Health Service?
A. I went to the National Institutes of Health for two years.
Q. Could you be kind enough to tell the ladies and gentlemen of the jury what the National Institutes of Health is?
A. Well, it's the -- I guess, one of the two

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major federal research and investigative organizations. I guess that's the best way to describe it.

Q. And for how long were you at the National Institutes of Health?

A. Two years. That's a standard rotation.

Q. And what did you do there?

A. Infections disease, mostly fungal disease.

Q. Would you tell the ladies and gentlemen of the jury just a little bit about what the field of infectious disease is, and then I'm going to follow up and ask you what fungal diseases are?

A. Infectious diseases covers microbial invasion by any organism. So viruses, bacteria, fungi, anthrax.

Q. Did you have a particular interest in fungal diseases?

A. I did.

Q. And can you just tell the ladies and gentlemen of the jury what you did at the NIH in regard to fungal diseases?

A. Well, I was investigating experimental treatment of major infections due to these organisms, these fungi. And the one that I was most

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interested in was called histoplasmosis, which is actually reasonably common in this area.

Q. This area being Wheeling and the Ohio River Valley?

A. Well, yeah, but this whole part, geographic region, of the United States. It's also very common in southeast, midwest.

Q. After you completed your tour of duty, so to speak, at the Public Health Service, did you then undertake a research fellowship at Cornell?

A. I did.

Q. And in what area was that?

A. That was infectious diseases.

Q. All right. And was that a one-year program?

A. Well, no, no. That was open ended, but, after a year plus, they asked me to go down to the Cornell division at Bellevue hospital in New York City and run their infectious disease service. I did that for ten years.

Q. All right. And was that basically the start of your academic career?

A. No. The start of the academic career was the National Institutes of Health.

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Q. Oh, okay. Now, I will come back to your academic positions in just a minute. I want to explore just a little bit more some of your areas of interest and specialization in the field of medicine.

You have talked a little about infectious disease. Would you please tell the ladies and gentlemen of the jury what the field of -- strike that.

Is there a field of medicine known as preventative medicine?

A. Sure. Preventive medicine.

Q. And would you tell the ladies and gentlemen of the jury what the field of preventative medicine is, give them a brief overview?

A. Yeah. It's sort of a hodgepodge. It includes infectious disease, immunization, health promotion and disease prevention, occupational medicine, epidemiology, statistics.

It sort of depends on the department. I mean, my department had certain specializations, and I have certain interests within it. But it's a very broad field.

Q. And is it at the current time a recognized

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specialty in medicine?

A. Oh, sure.

Q. Okay. You have indicated that you are the chairman emeritus of the Department of Preventative Medicine. How did you first happen to develop an interest in preventative medicine?

A. Well, I guess that started at Bellevue Hospital, because, when I got down there, knowing very little about it, we were inundated with IV drug users, heroin users.

And so I wrote a paper that, actually I think it's still one of the most read papers today, on the medical complications of heroin abuse. And because of that, I was asked to join the County Medical Society Public Health Committee,

And then I was asked to chair it, and then go Governor Rockefeller asked me to head his advisory group on substance abuse. And that sort of led to the dean at the New Jersey Medical School, who was sort of a mentor of mine for two decades, to ask if I would be willing to in essence, not go there as the chief of medicine, but, rather, switch and go there as the chief of preventive medicine and community health.

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Q. And I will follow up on that in just a minute.

Does screening or medical monitoring fall within the specialty of preventative medicine?

A. Sure.

Q. Doctor, are you familiar with the standards of care as applied to various screening methods used by preventative medicine physicians?

A. Yes.

Q. And are you also familiar with the standard of care as it applies to screening for particular diseases or conditions?

A. Yes.

Q. And do these include lung cancer, COPD and emphysema?

A. They do.

Q. Have you read and evaluated the current literature by Dr. Henschke and others relating to the use of low-dose helical CT scanning as a screening modality for detecting lung cancer?

A. Yeah. You asked if I have reviewed the literature?

Q. Yes.

A. Well, I don't necessarily know if I have

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reviewed all of the literature. But I have reviewed the major articles that are relevant to this case and have reviewed enough to make a very firm judgment.

Q. And just so we are clear, have you also reviewed and evaluated literature on the use of spirometry as a screening tool for COPD in smokers and former smokers?

A. Yes. Here again, I made no attempt to review the entire spirometry literature. I'm not a pulmonary physician. But as it pertains to this trial, should spirometry be used as a screening test in asymptomatic people, you bet.

Q. And just so we are clear, Doctor, I'm going to get back to the particular program that you have developed, and I will ask you some questions regarding spirometry and COPD and lung cancer in a minute.

A. Okay.

Q. Does preventative medicine include not only disease prevention, but also health promotion?

A. Oh, absolutely.

Q. And when you talk about health promotion, what is included in that?

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A. Well, health promotion can be screening, it can be self-administered actions, it can be immunization, it can be life-style changes. All of those are part of the program I developed.

Q. A few minutes ago, I think that you indicated, when I asked you what constituted the field of preventative medicine, you indicated that one of the areas was epidemiology?

A. It is.

Q. All right. And have you reviewed or monitored the epidemiology literature as it pertains to your areas of practice and teaching to keep current?

A. Well, do I keep current on all epidemiology? No.

Do I keep current on epidemiology as it relates to my major interest?

Q. Yes.

A. Oh, I have to. We have a web site relating to our program, and I do all the content for the web site and I have to review the epidemiology of virtually anything that's in the public press that relates to health promotion, disease prevention, because I have to put that on the web site with a

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judgment. So I don't review all epidemiology, but in my area, yeah, I review a lot of epidemiology.

Q. And sir, are you currently licensed to practice medicine?

A. I am.

Q. And in which state or states are you licensed?

A. Only New Jersey at present.

Q. Are you -- the jury has previously heard testimony regarding board certification.

A. Uh-huh.

Q. Are you board certified in the field of internal medicine?

A. I am.

Q. Are you a member of the American College of Physicians?

A. Well, that's not my -- you get to be a member bypassing the boards. That's not my current status in the American college.

Q. Did you become a fellow of the American College of Physicians?

A. I did.

Q. And how did that come to be?

A. You are elevated to fellow if you have

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passed your certification and you fit whatever criteria they decide to use to decide that you are suitable for advancment to fellowship.

Q. And after you first advanced to fellowship, did you thereafter become a master?

A. I am a master, yeah.

Q. And what does that mean or signify?

A. Well, the American College of Physicians selects -- I really don't know the number now. I became a master probably seven or eight years ago. At the time they picked about 30, 40 people from around the country and they had a committee that decided that you had done well enough, you had enough of a reputation, you had been productive enough to elevate you to master.

At the time I became master, I think, living and dead, there were something like two hundred and forty in the country. But that number has expanded obviously considerably since then.

Q. Are you also a fellow of the American College of Epidemiology?

A. I am.

Q. I believe I have previously asked you about your initial position at Cornell University. And I

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think you told us the fact you headed up the infectious disease research lab at Bellevue. I want to spend some time now talking about your responsibilities over the years at the University of Medicine and Dentistry of New Jersey.

I believe you told us how you were basically recruited to that position, and as I understand it, you were the chairman of the Department of Preventative Medicine and Community Health starting in about 1969?

A. '69. At Bellevue, I actually headed the clinical service.

Q. Okay.

A. So I ran the infectious disease service for Cornell, actually Columbia too. And, in '69, I left to become chair of preventive medicine.

Q. And that would be at the University of Medicine and Dentistry of New Jersey?

A. The New Jersey Medical School, which is part of the University of Medicine and Dentistry, right.

Q. And how long were you chairman of the Department of Preventative Medicine and Community Health at the University of Medicine and Dentistry

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of New Jersey?
A. About thirty years.
Q. Okay. And during that time, were you instrumental in building that department?
A. Oh, I built it from scratch.
Q. And can you tell the ladies and gentlemen just briefly what it is that department did and how it was that you built it?
A. Well, when I got there, it actually had only one person left, and I added epidemiologists and statisticians. We were asked by the federal government, because of my New York experience, to supervise and evaluate all the drug rehabilitation programs in Newark.
So we spent a lot of effort on that for a decade. And we decided it was important to build community centers in the central battered city. It was right after the riots. So we undertook that as a responsibility.
Then we decided that Newark was, still is, the most severely affected city in New Jersey, one of the most in the nation, with lead poisoning. So we determined we ought to screen every young child in Newark for lead poisoning.

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And meanwhile the deal for going over there was, I would still retain control of infectious diseases. So I did that, and then, almost right after I got there, I decided to look at health promotion, disease prevention, screening programs.

And I realized that there wasn't a good program in the United States, which seemed stunning. So a lot of my effort for the last 30 years has gone to develop that program.

Q. Okay. Now -- and I will come to that program in just a moment.

Over the years at the New Jersey Medical Center, have you been involved in teaching also?

A. Oh, sure. We were responsible for first year epidemiology and statistics, and second year epidemiology, preventive medicine. We run a nutrition course.

No, I don't do -- I never did all the teaching. I did -- that's what I have a faculty for. I did a small amount of teaching in each of those, but that was initially. I do very little undergraduate teaching now.

Q. Over the years, have you been involved in patient care?

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A. To an extent. I have never had a private practice. So, when I got to the New Jersey Medical School, I ran infectious disease. So that means I had a fellowship program, would make daily rounds and see patients. But any private patients I saw, I saw for my department. I got no money from them.

And that gradually dwindled as there were other responsibilities. I still see a small number of patients, but only for other doctors if they have been unable to solve problems. And differential diagnosis is my field.

Q. Over the years, have you had occasion to perform research in the field of preventative medicine, including infectious disease and cancer and things of that sort?

A. Oh, sure.

Q. And do you have publications in those areas?

A. Absolutely.

Q. All right. Let me just go through them just briefly. Do you have publications in the area of infectious disease?

A. Most of my publications are infectious disease.

Q. And have you had publications on the topic

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of cancer, including the incidence and mortality of cancer in New Jersey?

A. Yes. We looked at that.

Q. Okay. And have you looked at cancer rates and infections in cancer?

A. Cancer -- I'm sorry, could you give me that again?

Q. Yes. Have you done any work on areas such as cervical cancer ratios, infections in cancer and things of that sort?

A. Oh, sure. Sure.

Q. Now, I think you testified earlier that you had an interest and had been involved in health promotion and disease prevention. Have you had occasion to do any research and have any materials published with regard to health promotion and disease prevention?

A. Yes. I mean, articles in the medical literature, two books.

Q. I will get to your books in just a minute.

Have you published peer-reviewed publications that have included medical monitoring or screening as a subject matter?

A. As part of health promotion, disease

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prevention, sure.
Q. Okay.
A. Sure, that's part of our program.
Q. I do understand correctly that you have somewhere in excess of 320 publications in the medical and scientific literature?
A. Yeah. There are a few more that aren't on that list.
Q. Okay.
A. I will mention just one because we are really proud of it. We just had our major article accepted in a very good journal on why people exposed to HIV do not get the disease. And (A) we think we know why, and (B) we think we know what ought to be in a vaccine. So that's pretty exciting.
Q. All right. Let me -- in addition to the articles, have you had approximately eighty book chapters or monographs published?
A. That's correct.
Q. And those deal with infectious disease, public health, preventative medicine?
A. They do.
Q. And have you written a number of books?

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A. Five or six, depending on how you count.

Q. All right. Let me just talk about one or two of them briefly. You have published two volumes of a book entitled Your Healthy Body: Your Healthy Life?

A. That's right.

Q. Can you tell us generally what that book is about and what audience has been targeted?

A. Well, that and the prior book, which is called Stay Well, were for the public. They were not big sellers. That's one reason -- I naively thought that all we had to do was develop a good program based on good evidence and present it to the public and miracuously, providentially, everybody would say, isn't that marvelous and follow it. It just did not happen.

And that is the reason, in the end, we decided to see if we could make our program state law.

Q. Okay. And with regard to -- and I will get to your program in just a minute.

With regard to Your Healthy Body: Your Healthy Life, the book you just talked about, did that book basically suggest to the public that there were certain health promotion steps that they could take?

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A. Screening, health promotion. Of course, it's somewhat out of date. If I remember right, the second edition was published in '91. I think that's right. So our program now is a bit different from what was in the book.

Q. Now, Doctor, over the years, have you belonged to many medical societies?

A. I do.

Q. Okay. The American Public Health Association?

A. Yes.

Q. The American College of Preventative Medicine?

A. Yes.

Q. The Society for Epidemiological Research?

A. Yes.

Q. The American Society for Clinical Investigation?

A. Right.

Q. Have you, over the years, received awards and honors as a result of your work in the field of preventative medicine, medicine and infectious disease?

A. If you live long enough, you get some

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awards.
Q. I hope I live that long.
Now, I want to ask you a couple of questions about your program, which I will then go back to in some detail later.
A. Okay.
Q. So quite frankly, I'm not going to go through it in any detail right this minute. I just want to develop a few points for the Court and jury.
You have a program which is called "The New Jersey Health Life Program"?
A. No. Called just "Healthful Life."
Q. And you are one of the few people in the country who has actually designed a health promotion-disease prevention program that has been actually implemented and is in effect?
A. I think it's the only program that has the imprimatur of the state as state law. Of course, people design programs all the time, and I don't want to say how many are in effect. But in terms of a program that is state law and could become the national standard, yeah, I think we are the only one.
Q. Okay. And I want to just ask you a couple

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of things about it, and then later on I will go back and ask you about the details.

A. Okay.

Q. Do I understand, this program consists of 17 points, both medical and self-examinations?

A. We are just adding an 18th.

Q. Okay. And has this -- and this includes screening components; correct?

A. Of the 18 points -- of the 18 points, ten are screening tests, two are self-screening tests, and the other six points are either a miscellaneous category, includes immunization and tests for anemia, and the final four are lifestyle, including smoking cessation or not smoking.

Q. Okay. Has your program been published in the peer-reviewed literature?

A. Yes.

Q. And has it been endorsed by any particular medical organizations in New Jersey?

A. The state medical society has endorsed it actually very enthusiastically. The state nursing association, the New Jersey Public Health Association.

Q. And did you design your program in accord

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of accepted principles of screening and preventive medicine?

A. We did.

Q. And does your program reflect the state of the art as it applies to screening?

A. We believe it does.

MR. WOODSIDE: Your Honor, at this point in time, I would offer Dr. Louria as an expert in the fields of medicine, preventative medicine, health promotion and screening or medical monitoring.

THE COURT: All right. Any objection or do you wish to voir dire Dr. Louria?

MR. SEGAL: I have no objection, Your Honor. And I will reserve any voir dire for when it's my turn.

THE COURT: All right. This witness will be considered as an expert witness capable of giving opinions and conclusions within the disciplines of medicine generally, internal medicine specifically, preventive medicine and screening as part of a health promotion and disease prevention even more specifically.

Anything else?

MR. WOODSIDE: That would be fine.

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THE COURT: Is that it?
THE WITNESS: That's enough.
THE COURT: Does that cover it?
THE WITNESS: Yes, sir.
MR. WOODSIDE: Before I start, I don't know if you want any water or not and, if you do, I'm not sure that's new water.
THE WITNESS: I beg your pardon? How old?
THE COURT: It may be another experiment we need a Petri dish for.
MR. WOODSIDE: Do you want some water?
THE WITNESS: Well, I probably won't, but I would appreciate some new water.
THE COURT: We don't want to have you here without fresh water.
THE WITNESS: Right.
That's one of the perks of being a witness, somebody brings you water.
THE COURT: That may be the only one.
BY MR. WOODSIDE:
Q. Doctor, let me ask you a couple of questions about some of your litigation experience.
Have you ever testified in a lawsuit before at the request of a tobacco company?

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A. No.
Q. Have you ever testified before at my request or at the request of any of the defense lawyers representing the tobacco companies in this case?
A. No.
Q. As a physician who specializes in the field of preventative medicine, I'm sure you don't consider yourself to be a friend of the tobacco companies or an advocate for smoking?
A. I certainly am not.
Q. Are you being compensated for the time you have spent and are spending on this case?
A. I am.
Q. I'm going to ask you some questions today calling for you to offer opinions within the range of your expertise.
A. Uh-huh.
Q. Will you please offer only those opinions which you hold to a reasonable degree of medical certainty?
A. I will.
Q. Okay. I would like to ask you some background questions with regard to screening and

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then I will get more specific with regard to your program and the program in this case as we proceed.

A. Okay.

Q. I would like to know if the following is an accurate statement: Screening involves performing a medical test on an asymptomatic individual who is at risk for a specific disease in order to detect the disease at a stage when mortality can be reduced?

A. It is accurate as far as it goes. But it's not a complete definition.

Q. Okay. And would you please tell me what the complete definition would be?

A. All right. I am going to commingle screening and health promotion because they can't be divided.

Q. Okay.

A. What you do when you screen or do health promotion is try for -- you focus solely on primary and secondary prevention. Primary prevention is identification of a risk factor for disease that you then can modify. Example: High blood pressure as a cause of heart disease or stroke.

That's primary prevention. Primary prevention is risk factor modification, immunization is that.

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Secondary prevention is detecting a disease so early that, by intervening, you can prevent its full expression. That's largely why we do Pap smears, for example. Catch it so quickly that you don't get invasive cervical cancer.

The definition you read was perfectly okay, but mortality is the end point for screening for certain diseases; lung cancer, breast cancer, prostate cancer.

As far as I know, with all cancer screening, mortality is what -- is the end point you are looking to modify. But that's not true of all disease.

Q. Okay.

A. For example, you could do screening to prevent a nonfatal heart attack. So it's either mortality or incidence, incidence being defined as the occurrence of new disease.

Q. With regard to lung cancer screening, that involves performing a medical test on an asymptomatic individual who is at risk for developing lung cancer in order to detect the disease at an early stage when mortality can be reduced; correct? Talking about lung cancer.

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A. Yeah, I want to be sure to answer that. I apologize for this, but could you just repeat -- not the whole thing, but just the gist of what you are asking?

Q. With regard to screening for lung cancer, what you are trying to do is detect the disease at an early stage when mortality can be reduced; correct?

A. (A) mortality reduction is the only thing with lung cancer that you could measure, the only thing that would tell you whether a screening test is effective or ineffective.

(B) we have no screening test for lung cancer. We do have primary prevention. If you smoke, stop. If you don't smoke, don't start.

Q. Okay. So is it fair to say that -- strike that.

With regard to lung screening, do I understand the only measurement that counts is whether or not you can reduce mortality?

A. Absolutely. Every other measurement is so complicated and controversial and confounded, that it is not appropriate to urge mass screening on the basis of anything else except reduction in

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mortality.

I will tell you, Mr. Woodside, it is very simple. If you cannot show reduction in mortality, then all you can do with new screening tests is put them to the test. Do a proper trial and see whether they reduce mortality.

Q. Okay.

A. But no, no screening test for lung cancer is ready for general use if you cannot show reduction in mortality. Same is true with others, prostate cancer, for example.

Q. Let me ask you a follow-up. The jury has heard in this case some testimony about certain biases in the context of screening referred to as lead time bias, length time bias and overdiagnosis bias. Are you familiar with those biases?

A. Oh, yes, sure.

Q. Have those biases been studied and described in the screening literature long before this lawsuit?

A. Oh, good Lord, yes. Every time you do any screening test for cancer, any screening test, you run into those biases. You are detecting tumors that might not ever do damage, or you are detecting

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a tumor so early that all you are doing is doing exactly that, detecting it earlier, but not changing the course, the ultimate course, of disease.

And that is mortality. There is no other way you can measure it.

Q. All right. Let me ask you a couple of just very quick questions regarding these biases, then I have a little summary question.

A. Uh-huh.

Q. Are these biases real problems in evaluating the effectiveness of screening programs?

A. They are huge problems. Pardon me, in the absence of mortality data, you mean?

Q. Yes?

A. Oh, they are huge problems. They are problems that are so overwhelming that they prevent you from drawing conclusions. That's how serious they are.

Q. And are those biases problems which -- strike that.

If someone would attempt to evaluate a screening program based upon survival, would those biases affect survival time and therefore result in survival not being a reliable measurement of

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outcome?

A. Please define for me what the term "survival" means.

Q. Are you familiar with the fact, there has been some testimony in this case, you can have, for instance, five-year survival?

A. Oh, you can't draw any conclusions on that.

Q. And why not?

A. Because of all these problems. I mean, I mean, we went through this. We went through this with just x-rays when everybody said let's do these studies because, if you do x-rays as they did at the Mayo, every four months in heavy smokers, you are going to find it early, and you will change the course of the disease.

And so they looked at five-year survival. And, in some of the studies, they found that five-year survival looked better; some of them, it did not look better.

As soon as you followed them longer, you found that deaths were not changed. And the reason that perhaps the leading expert in screening in the United States, David Eddy, in 1989 wrote an article reviewing all the studies and said do not screen.

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1 That's why the U.S. Preventive Services Task
2 Force giving screening for lung cancer a
3 derecommendation. De means don't do. It doesn't
4 mean do it if you like doing it. It means don't
5 do.
6 Now we are going to go through the same thing
7 with helical CAT scan, and I will tell you, I mean,
8 I know it's disconcerting to people, but, if you
9 take shortcuts, you make mistakes. There is no way
10 that we would add helical CAT scan to our program
11 without mortality.
12 Q. I will get to that in just a minute.
13 A. Okay.
14 Q. Let me ask you a couple -- let me start
15 this way.
16 Are you familiar with the concept of evidence-
17 based medicine?
18 A. Of course.
19 Q. And could you just briefly tell the ladies
20 and gentlemen of the jury what that means?
21 A. Well, it sort of speaks for itself. It
22 says you try and base whatever treatment you do,
23 whatever screening you do, on the basis of evidence
24 that has -- for any test, for example, you need

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convergent evidence that has withstood the test of time.

And as one who has to review evidence, the three most worrisome words that I deal with are the three Ps: Potentially, possibly, probably; that people use those to circumvent having the evidence. You cannot do that.

Q. When you say "have the evidence," you mean that you have to have to have data that results from clinical trials and studies?

A. Yeah. You have to -- sure. You have to have data -- well, it doesn't have to be a clinical trial. It can be just observational. Like smoking. You don't need a clinical trial of giving people cigarettes and not cigarettes to see who gets lung cancer.

You just look at lung cancer rates and what percentage of them were heavy smokers, and you have got your data. So it doesn't always have to be a clinical trial. But screening --

Q. But you need data?

A. You need data, and, with screening tests, there is no way you can have a screening test without a proper trial, supported by other trials,

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withstood the test of time, and proper end points, lung cancer, end point, death or no death.

Q. With regard to screening for lung cancer, are there any such trials?

A. Well, there were. You mean new trials -- are you talking about helical --

Q. Yes. With regard to helical CT.

A. No. There is a trial being started that would be funded by the National Institutes of Health. That's the only controlled trial that I know of.

Q. Let me ask you a couple of questions about screening tests, safety, accuracy and efficacy, and I'm going to be asking these just generally. I'm not talking about CT yet, and I am getting to that in just a minute.

A. Pardon me, I would like to just amend the last to say that Henschke and her colleagues are the main proponents of helical CAT scan; that they may be -- they may be preparing a trial too, the nature of which I think is still unsettled.

Q. Okay. Earlier we discussed decreased mortality in some detail. Is evidence of a mortality benefit; that is, a decreased mortality, a

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measure of whether a cancer screening test or program is effective?

A. Yes.

Q. Okay. Is that the type of evidence that is necessary to demonstrate that a cancer screening test is effective and confers a benefit?

A. It's really, no matter how you slice it, it's the only measurement that we can use. It sounds seductive and great to say we will catch these tumors in the earliest stage and that's going to change the course of the disease. I mean, that's great.

But you have to show it works. And just saying we think it ought to work does not permit it to be used as mass screening.

Q. Okay. I want to touch on an area dealing with other characteristics of a valid screening test or program.

A screening program for cancer must be accurate S that a fair statement?

A. Well, I must say, I don't really use that term much. I know other people do.

Q. What do you --

A. I talk in terms of three things;

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sensitivity, specificity and predictive value of a positive.

Q. And does a test that carries a high false positive rate have poor specificity?

A. Yes.

Q. And what are the consequences of false positives?

A. The consequences of false positives, I mean, it depends -- let's talk about what we are here to discuss.

Q. Okay.

A. You mean lung cancer tests?

Q. Sure.

A. The consequences of a false positive are, one, psychological, of course, being misidentified. That can have huge consequences psychologically and in terms of quality of life.

Second, you have to sort them out, and that means invasive procedures. And that can result in complications of the procedure, and those complications would include hemorrhage, infection, lung collapse and occasionally death.

So you have to accept that, if spiral CAT scan were used, you would better know the benefits

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unequivocally, not controversially, unequivocally, because you can absolutely guarantee there are no free rides; and that some people are going to be hurt by this; and an occasional person is going to die. So if they are dying for no potential benefit, that's the worst case scenario.

Q. Let me ask you a question while I'm on this, and then I'm going to go to your program.

With regard to the proposal that there be helical CT screening for lung cancer in a class of plaintiffs in West Virginia, has it been shown that there would be any benefit whatsoever to those class members by getting screening with helical CT?

A. At present?

Q. Yes.

A. There is not a single life that has been demonstrated to be saved by helical CAT scan.

Q. Now, let me go to your program, and I want to ask you some questions about your program. I'm going to ask you about them -- your program generally, then I'm going to ask you a couple specific questions about your program that relate to COPD and lung cancer.

Could you tell us, again, the name of the

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health promotion, disease prevention plan that you designed that's been adopted by law in New Jersey?

A. The name of our program or the name of the law?

Q. The name of the program?

A. Healthful life.

Q. And are you the primary architect of that plan?

A. That's my program.

Q. And approximately how long did it take you to devise your program?

A. Well --

Q. And develop it?

A. Yeah. From 1970 until 1980, I and some of my colleagues reviewed the available literature and, in about 1980, came up with an initial program, continued analysis. In 1985, it became a 17-point program.

We tried to promote it, wrote the books. It wasn't very successful. Went to the legislature in '91 and to the governor. It was passed initially by the legislature in '93. It became law as the Health Wellness Promotion Act. And law and with its regulations, which you need to accompany the law, so

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that it started its implementation in November, 2000.

Q. One year ago?

A. One year ago.

THE COURT: Are you going to get into the program now?

MR. WOODSIDE: Yes, sir.

THE COURT: I want to give the jury two breaks this morning, if we can. So this might be a good place to stop before we get into the program.

MR. WOODSIDE: Yes, sir.

THE COURT: Let's just take about ten minutes. Doctor, you can move around if you want, just don't discuss your testimony with anyone. You are still on the witness stand.

THE WITNESS: Okay.

(A recess is taken.)

(In open court with a jury present.)

THE COURT: Be seated, please. All right, Mr. Woodside.

MR. WOODSIDE: Thank you, Your Honor.

BY MR. WOODSIDE:

Q. Dr. Louria, I believe I was about to ask you if you would give the jury an overview of the

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health promotion-disease prevention screening program that you have developed that's now in effect in New Jersey?

A. I would be delighted to do that. Mr. Woodside, I didn't get to fully answer your last question. Can I do that?

Q. Let's just start here.

A. All right. You want an overview of what?

Q. Of your program? What are the 17 or 18 points, just briefly tell the ladies and gentlemen of the jury what those are and what they are designed to achieve?

A. You trust my memory to particular off all 18.

Q. Actually, sir, I do. But I wrote them down in case --

A. I think that's very fortunate.

All right.

Q. Actually, Ms. Middelhoff wrote them down?

A. All right. There are ten screening tests. And those include Pap smears, mammograms, two tests for screening for bowel cancer, blood tests, that includes cholesterol, so-called good cholesterol, high density lipoprotein cholesterol, and glucose,

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1 blood sugar, blood pressure, glaucoma screening
2 and -- all right. I have named nine. Oh, yes,
3 osteoporosis screening. Those are the ten screening
4 tests.
5 Then there are two self-screens, and that's
6 self-breast exam for women and testicular self-
7 examination for men.
8 Then there are two additional tests that don't
9 fit either of the first two categories. One is
10 updated immunizations, which of course is critical,
11 and a second is hemoglobin test for anemia.
12 Then there are four life-style actions. One is
13 not smoking. A second is low back exercises. A
14 third is weight control. And a fourth is seatbelt
15 use all the time.
16 And that's it. Those are the -- we believe
17 that that is what every ostensibly healthy adult in
18 the United States should be doing to maximize his or
19 her chances of leading a longer and a healthier
20 life, and we do not think that we have excluded any
21 test that ought to be performed.
22 Q. And is your program evidence based? In
23 other words, is there data to support the decisions
24 you made in developing and recommending that program?

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A. Sure. And some of them -- I will give you a specific example. In glaucoma testing, we have taken controversial evidence that is still unsettled, and we have made a judgment about it and decided that we would do it.

Now, almost everybody else in major screening programs now does glaucoma screening, there is a little difference in time lines. But again, we are not advertising that everybody agrees that the evidence is incontrovertable.

We are saying we looked at the evidence, there is plenty of evidence out there, and this is the judgment we came to. With others, Pap smears, bowel screening, mammography -- let me remove the last one -- with bowel screening, with Pap smears, for example, blood pressure screening, cholesterol screening, there is now no debate. Everybody agrees that the evidence is overwhelming.

So what I'm saying is, everything we do, we look at the evidence. Everything we do. You can't do it without the evidence.

But we then make judgments about the evidence, and not everything in our 18 points will necessarily be identical to, say, the U.S. Preventive Services

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Task Force.

They look at the same evidence, they may have a slightly different judgment, but I will tell you there are no major disagreements.

Q. Now, does your program contain recommendations for screening smokers and former smokers for lung cancer?

A. Screening as opposed to telling them not to smoke?

Q. Just screening. Does your program contain recommendations for screening smokers and former smokers for lung cancer?

A. It does not, because there is no screening test that has been shown to reduce mortality -- that is, deaths -- to a statistically significant extent, and that is what you must show. And now I got in the answer that I wanted to get in from the last question.

Q. Well, that was only because I couldn't remember the question before.

Does your program contain recommendations for screening smokers and former smokers for COPD or emphysema?

A. No.

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Q. Why not?

A. Because there isn't any rationale for doing that. What you do with smokers is you say to them, if you keep smoking, especially if you are smoking heavily for a long period of time, you have -- you are going to damage your lungs. So stop smoking.

Spirometry adds absolutely nothing to that advice. Whatever the spirometry tests -- can be normal, borderline, slightly mildly abnormal, moderately abnormal, severely abnormal.

For every one of those, every single one of those five possible outcomes with spirometric testing, the approach is identical. If you are smoking, stop smoking. If you are an ex-smoker, don't go back. So why do spirometry? There is no rationale for it.

Q. All right. Doctor -- excuse me, I have a cold.

You are aware that, in this particular lawsuit, plaintiffs are asking for screening procedures for class members which would include helical CT screening annually beginning at age 50, and then spirometry at age 40 and then 45 and then every two years thereafter. Are you aware of that?

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A. I am, sure.
Q. Are you aware of any major public health organization in the United States that has recommended or endorsed such a program to screen large numbers of smokers and nonsmokers?
A. I am not.
Q. Doctor, I'm just reviewing my notes, here.
MR. WOODSIDE: I have no further questions.
THE COURT: All right. Cross-examination?
MR. SEGAL: Thank you. Good morning, ladies and gentlemen.

-- -- --

CROSS-EXAMINATION

BY MR. SEGAL:
Q. Dr. Louria, we have not been introduced. My name is Scott Segal?
A. Oh, I know.
Q. If I ask you any questions -- we checked your books out. If I ask you any questions that don't make sense or you want me to rephrase it, you just ask me to do that, and I will keep rephrasing it until we both feel comfortable with it.
A. Thank you, I wouldn't be diffident.
Q. Two things I want to clear up about the

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direct examination and prior experience.

First, the compensation issue. When you are out of town, it's my understanding that tobacco -- the compensation is seven thousand dollars per day when you are out of town; is that correct?

A. For being out of town?

Q. Yes, to be here. You charge five thousand dollars a day, but there is an extra two thousand if you have to --

A. No. I charge five thousand dollars for subjecting myself to this in court, for court testimony. And I charge three thousand dollars for if I have to leave Newark in a plane.

Q. All right. And you will be here a total of two days?

A. No. It will be one -- that does not include the day I testify. So one day.

Q. The other thing is, you said -- you were asked some questions about other tobacco lawyers and other tobacco testimony.

A. Uh-huh.

Q. You have testified on behalf of the tobacco industry in another case in Louisiana; correct?

A. I have?

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Q. You have given testimony -- you know, when they put you under oath --

A. You mean did I have a deposition?

Q. Well, do you not that, when you give a deposition --

A. I understand that. But I have not testified in Louisiana. Indeed, I have not heard one word since the deposition --

Q. Okay.

A -- so I presume I'm not involved in that anymore.

Q. All I want them to understand is, you have given testimony, not in a courtroom --

A. Oh, sure. I gave a deposition.

Q. All right. And that was another medical monitoring case in Louisiana in which you disagreed with the medical monitoring program submitted -- forget what it was, I don't want to get into that -- but you disagreed with a program, a monitoring regimen, for cigarette smokers in Louisiana?

A. Sure. It's another Dr. Burns case, right.

Q. Now, I want to talk, though, about some of your earlier experiences that you mentioned. First of all, the program in New Jersey which you were

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doing is for everybody who lives in New Jersey. What I mean by that is it doesn't matter if you have been exposed to lead or to a work environment which may expose you to some different toxins.

The program of which you have spoken of today is for all New Jersey people; correct?

A. It is for all ostensibly healthy adults in the state of New Jersey and, we hope, nationally.

Q. That's your goal. You want this program to be adopted nationally; right?

A. That's what we are working for. It's already been introduced into two legislatures.

Q. Okay. But what I want them to understand is, though, you don't in that program identify subgroups and say we ought to screen these too. It's a program for all ostensibly healthy adults in the population; correct?

A. No, wait a minute, Mr. Segal. The subgroups are -- I mean, subgroups are automatically included if there is any major problem affecting them so that women are a subgroup, and we do mammogram screening because of breast cancer. Smokers are a subgroup because they, of course, are subject to a lot of diseases.

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And so it's just not fair to say these are all healthy people without risk factors. But you are absolutely right, it applies to everybody, but in consideration of how we developed it, of course we considered subgroups.

Q. Okay. Well, for instance, does your program recommend that all children in Newark receive lead poisoning screening?

A. It might if it applied to children. It doesn't. As you well know, because you got the book, this is a program for adults.

Q. Right.

A. So we start at age twenty.

Q. Let's use another example. In the State of New Jersey -- these aren't the only screening tests available to the citizens of New Jersey who have been exposed to things; correct?

A. Oh, of course not.

Q. For instance -- they don't know this, but I'm sure you do, being from New Jersey -- everyone in New Jersey as of this year -- actually last year, but this year or last year so we don't fuss about it, who was exposed to the drugs Pondimin and Redux can get a free echocardiogram; correct?

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A. That may be true. I haven't looked at it.
Q. But that's not part of your program? That's a different screening program because of a discrete exposure, the drugs Pondimin and Redux?
A. Because they are presumably given to people because of presumed diseases. You are right, once you develop the disease, then you don't fall under our health promotion-disease prevention program.
And I appreciate your bringing that up because I head the advisory board to the Health Wellness Promotion Act that advises the legislature, and we asked the legislature to give us proposed legislation relating to health promotion-disease prevention before it goes very far to give them expert advice.
When we get that, if it turns out that the bill they submitted us is actually a bill for somebody who has already got a disease, we reject it as saying that doesn't come under the purview of this.
So you are absolutely correct. Once you are being given drugs for a disease, you wouldn't fall under our program.
Q. Right. And those drugs weren't given for a disease. They were given for weight reduction?

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A. The complications of a drug treatment would not fall under us.

Q. Okay.

A. A weight control would.

Q. Because you recommend weight control as one of the four life-style factors, that's in your program; right?

A. Yeah. I mean, your point is well taken. I will tell you, I really hadn't considered what you were saying. But you are right, there is some overlap because, as you well know, what we advise is for those who have body mass indexes over 27, that your first approach is life-style, so we want you to exercise and watch what you eat and then, if that doesn't work, we said, under medical supervision, you can -- you may be given medication, sure.

Q. Now, the next area I want to talk about is the area that you mentioned involving the lead screening for children in Newark. A serious problem with the old buildings containing lead paint to which these children are often exposed tragically and unfortunately; correct?

A. That's not the basic problem that we are addressing. That is one of the issues.

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Q. Okay. How do you screen children for lead toxicity, or how did you, I guess I should say?

A. No. One of our major projects now is the nutritional approach to lead poisoning. The program is called "Calcium In, Lead Out." Look, I will be very brief on that because it's a big issue, and it's not really germane to this.

Q. I don't want to --

A. The answer is: You can't really effectively combat the lead problem by screening children, which we do. We do blood tests. But, if you screen them and the blood test is high, they are already poisoned, and their brains are involved.

So what we focus on is how you reduce that. We don't pay as much attention of doing the blood screen as we do about nutrition. Get enough calcium, and your problem is going to diminish.

Q. All I wanted to point out, in your program in New Jersey, in Newark, you do a screening test on children to determine whether or not they have a toxic level of lead; is that correct?

A. You mean totally unrelated to healthful life? It has nothing to do with the Healthful Life Program.

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Q. Correct.
A. We do not do the screening. The state does the screening. We do the education and nutritional intervention.
Q. All right. If that blood test is high, okay, some of those children -- "some" is my word -- of those children will suffer brain damage; correct?
A. Correct.
Q. That brain damage is irreversible; correct?
A. It is largely irreversible.
Q. With regards to health for life -- no, I want to talk to you about one other thing.
A. Healthful life.
Q. Healthful life. But I want to talk to you about something else now. You said prostate cancer is an example was kind of how the answer came out?
A. Right.
Q. And when you were talking about that, you were talking about there is no mortality data to substantiate the use of certain screening tests in the diagnosis of prostate cancer; correct?
A. Correct.
Q. All right. But there are still organizations, good organizations, in the United

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States who recommend that men over the age of 50 have an annual prostate screening examination?

A. Not the major screening groups. The U.S. Preventive Services Task Force gives it a de, do not do. We do not recommend it. The Canadian task force doesn't.

If you can tell me other than -- I mean, there are special interest groups that are good. I don't want to disparage them. So urologists recommend it.

Q. There you go.

A. Of course they do. Of course they do.

Q. Okay.

A. Just like some of the pulmonologists will support your spirometry. But that's very different from what we hope are impartial, evidence based screening-focused health promotion, disease prevention focused groups. Now, maybe you can tell me one. I know it's being reviewed by the American College of Physicians --

Q. That was fine when you said urologists.

A. I don't know any group. The urologists. Oh, sure, the urologists would like to do it every three days.

Q. Now, you mentioned the guide -- when you

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talk about the preventive health service people, the Guide to Clinical Preventive Services is the publication you have been talking about?

A. Which one have you got there? The 1996 one?

Q. It says Report of the U.S. Preventive Services Task Force, Second Edition.

A. Yeah, that's 1996.

Q. This one actually says 1989, First Edition. 1996, Second Edition?

A. 1996, yes.

Q. Now, here is what I want these folks to understand. You talked about these people, but, when you were giving them the list of the ten screens and you were talking about morbidity versus evidence based; okay?

A. Yes.

Q. When you used your judgment, Dr. Louria, you don't always agree with these people, do you?

A. Well, let me be very careful on that, because we have had a long dialogue with them, and I want the Court and you and the jury to understand. The answer in general is absolutely, we are not identical.

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1 But the issue that they raised when our program
2 came out and received all of the press attention
3 was: Do you include in your program anything that
4 we give bad recommendations, D or E.
5 And I said, no.
6 And then they said, Do you agree with all our A
7 and B, our high recommendations?
8 And I said, after looking that through page by
9 page, that we do virtually everything you give that
10 recommendation to with the exception we are not
11 going to do Chlamydial screening because we can't
12 figure out who to screen.
13 So where our differences are is their C
14 recommendations, which say there is not enough
15 evidence for or against.
16 Now, as you well know, they are updating
17 those. They have just moved areas that we thought
18 were somewhat different because we were -- we had a
19 C recommendation of theirs, they have just changed
20 major ones to B and A recommendations.
21 Our disagreements now are minimal. But I will
22 give you just one example. I don't want to take
23 time, but I will give you a recommendation of a C
24 recommendation.

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We urge people to do low-back exercises every day because it's a major cause for disability for work because we think it works. They give that a C recommendation so they would say we don't think the evidence is enough for a firm recommendation for it. And we say we absolutely agree with you, but by the way, our judgment is we are going to recommend it anyway.

So that I will tell you, differences between us and the U.S. Preventive Services Task Force is virtually off the table now because, not only do we virtually agree, but also one of their members is one of my closest associates in the Healthful Life.

Q. Let's go back to my question.

A. I'm sorry. I thought I did.

Q. Let's use some specific examples; okay?

A. Uh-huh.

Q. For instance, in their second edition, they recommended that women receive mammography beginning at age 50; is that correct?

A. Yes, they have just changed that.

Q. But in their second edition, that's what they recommended; right?

A. Sure. That's six or seven years old.

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Q. And your recommendations to the New Jersey Legislature are six or seven years old and being updated now; correct?
A. That is -- yeah.
Q. And Dr. Louria --
A. That's correct.
Q. And Dr. Louria, in his recommendations six or seven years ago which are now being updated, recommended that women should begin the mammography screening at age 40 because Dr. Louria believed there was enough evidence based data to suggest that it would indeed be beneficial and ultimately proven to reduce mortality; correct?
A. Not quite. That has been my judgment not for six or seven years, but for fifteen years. Since 1985.
Q. Other than that, was it a correct statement?
A. No. We looked at studies that showed a mortality benefit, mortality benefit, and said that we believe that these studies are valid enough for us to include it.
Q. Okay. And at beginning at age 40 and they say age 50; correct?
A. No longer. They now say age 40. We were

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right.
Q. In the second edition?
A. Sure.
Q. Okay. Second edition says that you should begin the screening for intestinal cancer, you should begin that screening at age 50?
A. Yes.
Q. Dr. Louria said, when he recommended it six or seven years ago to the legislature, you ought to begin that at age 40?
A. For Hemmocult and 45 for flexible sigmoidoscopy, and we are just adding a colonoscopy alternative, right.
Q. And the second edition did not recommend self-examination for testicular cancer?
A. Absolutely correct.
Q. Specifically did -- incorrect?
A. Correct. They give a C recommendation, not evidence for or against.
Q. I want to make sure I got the words right. They say there is insufficient evidence to recommend it?
A. That's right. It's a C recommendation. Mr. Segal, there is nothing wrong with looking at

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the evidence and drawing somewhat different conclusions that are then subject to the scrutiny of your colleagues.

The problem is if you draw conclusions that are not based on evidence. We will never be identical to the U.S. Preventive Services Task Force. We are reading the same literature, we are reading the same evidence.

I have a perfect right to come to a different conclusion, and they have an absolute right to contest my conclusion. But neither of us has a right to make a recommendation that's not based on any evidence.

Q. Okay. Now, you are aware of the Journal of Respiratory Diseases, although you are not a pulnongist. You are aware of that journal, the Journal of Respiratory Diseases?

A. Sure. I even had an article in there.

Q. And am I correct, there were one, two, three, four, five, six, seven, eight, nine contributors to the special edition that they printed on early detection and management of COPD. Is that correct?

A. Show me the article.

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MR. SEGAL: Sure. May I approach, Your Honor?
THE WITNESS: Is that the Ferguson article. No, that's not the Ferguson article, is it?
THE COURT: You will see it in a minute, here.
THE WITNESS: Okay.
BY MR. SEGAL:
Q. Now --
MR. WOODSIDE: Your Honor, I can't tell what article this is because it's only one page here.
MR. SEGAL: I just wanted to go over the fundamental truths about COPD.
MR. WOODSIDE: Objection.
MR. GREUNLOH: It's already been used.
THE COURT: What's the specific objection?
MR. SEGAL: Yes. It's been previously used with several witnesses, Your Honor.
THE COURT: It was used as a demonstrative aid, or has it been admitted into evidence?
MR. WOODSIDE: Neither.
MR. GREUNLOH: I have a copy.
THE COURT: All right. What's the specific objection? Do you want to come up?
(At sidebar:)
MR. SEGAL: You saw this on the board, and you

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said I didn't use it as a demonstrative.

MR. WOODSIDE: Here is my problem. I object to having one page without having or denying the doctor an opportunity to look at the entire article. We can't tell who the author is or anything.

MR. SEGAL: This is -- you and I have both used this before.

MR. WOODSIDE: Then let's start with the first page and use the article.

MR. SEGAL: I will be happy to give that to him if that's what you want.

MR. WOODSIDE: That's what I'm asking.

MR. SEGAL: I will give it to the witness.

MR. WOODSIDE: I believe this is the article, the last time we talked about this, this is the article which recommend's that there be cessation programs, and if this is the article that recommends the cessation program, we got into it before, and I want to object on that basis, because I believe he's going to open the door on cessation.

THE COURT: They are into the 18-point program in which -- I mean, it's going to stop at that point. But that's part of what you have laid before the jury in terms of this gentlemen's

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recommendations.

MR. WOODSIDE: All he said, he recommended quitting. This paper, I believe, goes on and says one of the things you use spirometry is then you use the spirometry results to tell the people you ought to quit, and it's an adjunct to cessation. And that's not part of this case.

MR. SEGAL: And it's not going to be, with what I intend to do with this article.

MR. WOODSIDE: In this case, I suggest he look at the entire article. But if he's not going to go into that, my objection is that it would be premature.

THE COURT: What you should do in order for it -- just to have it complete. But specifically we have to be very careful that he does not somehow -- well, that's the danger with this witness is every expert on all sides. Everybody has a lecture to give to this jury.

MR. SEGAL: I have done my best to try to say am I correct and go back to my question. I just can't get him there.

THE COURT: I understand that. That's the nature of the beast. And we have come this far.

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I'm not going to clamp down. We simply have got to be careful.

If he gets into some of these areas that spirometry is somehow a part of a modality for a cessation program, I have to stop him.

MR. SEGAL: Let me ask this, Your Honor. Do you object to the Judge leaning over and just asking the witness without the jury hearing that he's doing it, just ask the witness to try and respond succinctly to the question? I mean is that too much to ask at this point?

MR. WOODSIDE: Here is my problem. I think the Judge touched on it. Experts on both sides have done the same thing. I think, Counsel, that all of us try to do our best, and I would object to the extent it would look bad in front of the jury.

But Your Honor, here is the problem I have got with this particular --

MR. SEGAL: Can I give this to him so he can be looking at it so that's all right?

THE COURT: Sure.

MR. SEGAL: Here you are, Doctor.

MR. WOODSIDE: I'm not sure what Mr. Segal is going to do with this. Here is the problem --

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MR. SEGAL: Here it is.
MR. WOODSIDE: Just one minute. Are you going to show this on the screen, because, you see, we get down to successful cessation programs?
MR. SEGAL: No. I'm not going to show it on the screen if he agrees with me.
THE COURT: You are going to first talk about the first bullet point?
MR. SEGAL: Yes, yes, but not only.
Former and current.
MR. WOODSIDE: Okay.
MR. SEGAL: And I will ask him whether or not there are any -- I don't intend to read them, but COPD patients who are at risk for increased morbidity and mortality and should receive influenza pneumococcal and the one right after that.
Let me state why. He's trying to give the impression there is no treatment for COPD except quitting. And that's not true.
MR. WOODSIDE: No. We have not talked about treating COPD. He simply talked about quitting. I didn't get into that.
MR. SEGAL: He said that's the only thing you can do. Remember, he said, even if you get it, if

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it's normal, abnormal, mildly abnormal, moderately abnormal or severely abnormal, the only thing you can do is quit. That's not what these people said.

MR. WOODSIDE: I would object to any interjection in this case. The last witness in influenza pneumococcal vaccines. I'm objecting to that.

MR. SEGAL: I'm aasking aren't there treatments that they are recommending for people who have COPD. You are right, I'm not going to get into it. If he says there are treatments they recommend, then I will move on.

THE COURT: I'm going to permit it because I think it's proper cross-examination. Obviously, two bullets we are talking about are appropriate. The third bullet point should be -- I really have to wait to see what his answer is.

There is no question he did indicate that the only -- spirometry is irrelevant is what he is saying. It's absolutely not necessary. Thus the only real treatment is to stop. And, to the extent that there is evidence from this group of folks that suggests otherwise, you can use it.

MR. WOODSIDE: So we are clear, we are not

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going to talking about smoking cessation programs?
MR. SEGAL: No.
MR. WOODSIDE: Okay.
THE COURT: And I will be rather vigilent.
MR. WOODSIDE: Thank you.
(In open court:)
THE COURT: All right. Mr. Segal, you want to continue?
MR. SEGAL: Yes, Your Honor, please.
BY MR. SEGAL:
Q. Dr. Louria, if you would, in the article, or actually it was the supplement to the Journal of Respiratory Diseases, Early Detection and Management of COPD -- the jury has seen this before. These are a group of pulmonologists who are making certain recommendations about people who do smoke and who have formerly smoked; correct?
A. This is a group of pulmonologists called the National COPD Awareness Panel who want primary care doctors to do spirometry in their offices, a catastrophic recommendation.
Q. And fundamental truths about COPD for primary care clinicians, Table 1, do you see Table 1?

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A. I do.
Q. All right. Do you agree with me that they recommend, the pulmonologists, do you recall -- let me ask you something first before we get there.
Do you recall you told the jury that, if you have a spirometry, whether it's normal, borderline, mildly abnormal, moderately abnormal, or --
A. Severely.
Q. Severely abnormal, the only thing you can do is quit. Do you remember that testimony?
A. If you are an asymptomatic smoker, the only known treatment is quit. And our pulmonologists do not agree with this recommendation. I just checked it with them.
Q. I only want to point out that COPD can be treated and the disease process altered; that's their conclusion in Table 1; correct? You can read it word for word?
A. No. I read it. But you are taking it out of context. Symptomatic COPD, symptomatic, can be treated for symptomatic exacerbations with bronchodilators or antibiotics if needed. Symptomatic.
So that has nothing to do with screening

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asymptomatic people. Asymptomatic people, the only treatment, the only treatment is stop smoking. And they don't disagree with that.

And furthermore, the treatment for symptomatic COPD, which is only detected by spirometry in about 25 percent of symptomatic people -- that's how insensitive it is -- the only effective treatment that changes the course of their disease is stopping smoking.

So you and I agree. I mean, what I said is absolutely correct, Mr. Segal.

Q. All right. And they say that COPD can be treated; correct?

A. The only way to change the course of COPD is stopping smoking. What they are talking about is symptomatic relief when you have an exacerbation. Now, that's clinical disease.

I'm not suggesting that people who have clinical COPD should not have spirometry to monitor them. I'm not suggesting that at all. I'm saying a screening test, as you well know, is for asymptomatic people.

For those people, I don't care what you find on spirometry, your advice to them is: Stop smoking or

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you will hurt your lungs. And, if you never do a spirometry, your advice to them is: Stop smoking or you will hurt your lungs.

Q. And they do say that former and current smokers, even if asymptomatic, should undergo spirometry testing at least annually?

A. Why? I mean, that's the question I asked them: Why? I asked it to our pulmonologists, I showed them the companion article by Ferguson and said, Why would you do it? And they say --

THE COURT: Well, Doctor, if you could first answer the question and then, if you want to, then expand it, you can do that, or explain it, you can do that. But there is a specific question that has been asked.

THE WITNESS: Sure. Shoot.

BY MR. SEGAL:

Q. All I wanted to know, Doctor, was, this group of pulmonologists recommends, both for former and current smokers, even if asymptomatic, they should undergo spirometry testing at least annually?

A. That is correct.

Q. Now, another area I want to cover is some of your views on cancer, and I want to look, if we

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can, at Pages 32 and 33 of your book Stay Well. Okay?

MR. SEGAL: May I approach, Your Honor?

THE COURT: Yes.

MR. SEGAL: May I approach, Your Honor?

THE COURT: Yes.

MR. SEGAL: Ms. Gina, That's tab 10. It's Pages 32.

BY MR. SEGAL:

Q. When did you first publish Stay Well, Dr. Louria?

A. It's only been published once. You would have to tell me. I would guess 1982. Am I right?

Q. I think it was -- one was 1980, and one was 1989. So, if this was the first one, then it would be 1980. I will double-check.

A. You are right, no, I'm sure you are right. So actually that book, that book was published before our program --

Q. Copyrighted, 1982, you were right, sorry.

A. Yeah.

Q. 1982?

A. Right at the beginning of our program, right.

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Q. Here it is. Can we please go to the:
I would emphasize that there are three somewhat dispar rate approaches to cancer: (1) total prevention; (2) early detection and effective treatment before invasion or spread has occurred; and (3) effective treatment after the tumor is established.
Did I read that correctly?
A. You did.
Q. Any cancer is easier to treat when it is localized. The five-year survival rate of the cancer when it is localized as compared to when it has spread to at least some extent for eight major tumor sites is shown in Table 3.
Did I read that correctly?
A. Yeah, you did.
Q. If we could go to the next page. And in Table 3 you note that the percentage of persons surviving five years if the cancer is localized is up to 65 percent in lung cancer as compared with only 9 to 13 percent if the cancer has spread?
A. Correct.
Q. And then you conclude:
There is, then, a tremendous difference

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in outcome if the tumor is localized at the time of discovery, and this is true even for cancers with a terrible overall outcome.

Did I read your words correctly?

A. You did.

Q. And Doctor, you told these folks about complications with the use of early detection of lung cancer.

A. Right.

Q. Well, in addition to your words, I want to talk to you about -- you referenced the Mayo study. Do you recall that?

A. It's one of the --

Q. In your testimony?

A. I mentioned it, yeah.

Q. Now, the Mayo study looked at over nine thousand people; correct?

A. Right.

Q. And they did find improved survivability in five, ten-year and fifteen-year groups; correct?

A. No, I don't think so.

MR. SEGAL: All right. Let's put up -- can you put this up?

MR. SEGAL: May I approach, Your Honor?

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THE COURT: All right.
BY MR. SEGAL:
Q. Under the --
A. Oh, yeah. Yeah. No, I was just remarking for myself.
Q. Okay. So they did in here find that survival was better for those who were screened versus those who were not screened for the five-year group, for the ten-year group and for the fifteen-year group; correct?
A. No.
Q. Sir, I didn't say mortality.
A. No, but as long as everybody in this room understands that this is the article that says there was no benefit and, (B), that this curve is exactly what Pamela Marcus was talking about.
This is survivability from the time of diagnosis. So that it is -- as she points out, that's the overdiagnosis bias. Her conclusion, as you well know, is that it was ineffective.
Q. Right, in fact, they stopped doing it?
A. Stopped doing what?
Q. The x-rays screening.
A. Sure.

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Q. These folks stopped recommending it based upon these studies?

A. Us, too. Remember, the book you showed was done before those studies -- my book -- was done before it was completed. We all stopped recommending x-rays.

Q. And here is what I want to get to, though --

A. Sure.

Q -- they did improve survivability, not mortality, in the five, ten and fifteen-year groups that they looked at; correct?

A. Except for adenocarcinoma; correct?

Q. I'm just talking about their general conclusions. Here, let's just read it.

A. Right.

Q. It's the paragraph that's highlighted right here, please.

A. No, you are right, except if you look above that paragraph --

Q. I'm going to read the whole thing for you, Doctor.

MR. SEGAL: I need the lines above it, Ms. Gina.

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A. Mr. Segal, read above that.
THE COURT: That's what he's trying to do.
BY MR. SEGAL:
Q. Extended follow-up of the MLP participants indicates that an intense six-year screening regimen of chest x-ray and sputum cytology did not reduce lung cancer mortality, the most important and meaningful end point in trials of mass screening.
However, individuals in the intervention arm who were diagnosed with lung cancer prior to July 1, 1983, had better survival than their counterparts in the usual-care arm.
Did I read that correctly?
A. You read that correctly.
Q. And I read the part you wanted me to read about the mortality?
A. No, sir.
Q. Read above that?
A. I wanted you to give me the whole page and let me just see the last line of the -- no, you can do it. Look at the last -- because what helical CAT scan picks up is adenocarcinoma. Look at the last line just before discussion.

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Q. Right here. Blow that paragraph up?
A. Do you want me to read it.
Q. For small and large cell histologies, differences in lung cancer survival were observed, but they were not statistically significant in. The case of adenocarcinoma, the two arms had similar lung cancer survival?
A. My point being, since helical CAT scan picks up adenocarcinoma, that even using that it did not apply for adenocarcinoma. And that's what the helical CAT scan is all about.
Q. Here is what I want to get to, though. That study involved over nine thousand people.
A. It did.
Q. It involved attempting to early detect lung cancer?
A. Yes.
Q. Okay. That study also was part of a review article that you have seen that involved the Czechoslovakian study, a Sloan-Kettering study, the Mayo study and the Hopkins study; right?
A. You are talking about the Eddy article?
Q. Yeah.
A. In 1989?

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Q. Yes.
A. Yes.
Q. And nobody, nobody has reported one single fatality in an individual with a benign lung condition, not one single reported fatality of an individual with a benign nodule?
A. I wasn't aware that was the purpose of the article or had anything to do with it or that Eddy ever looked at that. Eddy wouldn't have looked at that.
Q. You don't recall that in each of those articles they reported when people died?
A. But that doesn't mean that they would report a consequence of a false positive. Maybe they did. You may be right.
Q. So what you are saying, I'm wrong and there were false positives and people were dying right and left and they failed to report it?
A. No, no, I'm not saying that. I'm saying that those articles would not necessarily focus on a single adverse effect. I will just tell you from my own experiences they are going to have adverse effects.
Q. But they did not report, not a single one

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of those researchers, which involves over 85,000 people undergoing chest x-ray screenings, they did not report one single fatality from a nodule that was benign?

A. I'm sorry, when I read those articles, I didn't see any section that talked about that.

Q. And Henschke specifically has reported in over a thousand cases that there hasn't been one single fatality as a result of a benign nodule; correct?

A. That's correct.

THE COURT: Are you at a point where we can --

MR. SEGAL: Sure, Judge.

THE COURT: -- stop?

MR. SEGAL: Yes.

THE COURT: Let's take a break now. This will be the last break in the morning.

Doctor, you can walk around. Again, don't discuss your testimony with anyone. Thank you.

THE WITNESS: Okay, Judge Recht.

(A recess is taken.)

(In open court with a jury present.)

THE COURT: Be seated. All right, Mr. Segal?

BY MR. SEGAL:

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Q. Doctor, to wrap up what we were just talking about, in all fairness to you, you are not an oncologist or someone who regularly diagnoses lung cancer in people; correct?

A. That's correct.

Q. And you don't do fine needle biopsies or CT assisted fine needle biopsies or video assisted fine needle biopsies; that's not something you do?

A. No. I only would get involved if there was a complication.

Q. And you are aware that, unlike the Mayo studies done years ago, the newer studies, there is an evolving methodology for doing biopsies to reduce the risk of biopsies; correct?

A. Mr. Segal, any invasive procedure carries with it potentially catastrophic results. And I don't care how much you reduce the risk, I would guarantee you on the basis of my own experience of more than forty years that, you do it as a mass program, somebody is going to die while you investigate the positives. Just from anesthesia, for example.

Q. But that has not occurred in the Henschke study to anybody, not one single soul has that

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occurred to?

A. Well, that's irrelevant. It's a small -- in the first place, that is a small study. It's a small study.

Q. A thousand people?

A. Yeah. It's a small study. We are talking about mass screening. Mass screening, there would be -- it depends on how you want to look at it. 20 to more than 50 percent false positives in West Virginia. 20 to 50 percent.

Q. And in fact, there would be 20 percent false positives in any mammography screening program, wouldn't there? Your own book says that, 20 percent false positives, and that's if it's read well.

Isn't that what you said in your book? Any mammography program would have 20 percent false positives even if read by a competent mammography reader.

Am I misquoting you?

A. Look at the date on it.

Q. I'm not --

A. You are not misquoting me, but that is not -- it's not nearly that bad. But, of course,

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the predictive value of a positive for mammography is still, I would say, in the 30, 40 percent range, meaning, if you get a positive, 30 to 40 percent of many of the time, you will have cancer and, the other, times you won't.

For the lung, it is, based on both Henschke's studies and Sone studies, the predictive value of a positive is in the range of 10 to 12 percent. Now, all of the rest of those nodules are false positives,

And I will tell you, working up a breast nodule is very different from working up a lung nodule.

Q. Indeed, because, as the jury has seen in the very articles, before you would ever stick a needle in a human being, there are all types of follow-up scans you can do before you ever get to the invasive procedure; correct?

A. No. In the lung?

Q. In the lung.

A. In the lung, you are going to have invasive procedures. Look at Sone's study. Sone's study -- the two big studies are Sone's and Henschke's -- and see what he says about how they work it up. They do more CAT scans. Then they do transbronchial lung

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biopsies.

There are going to be people who end up with unsure diagnoses, for example, adenomatous hyperplasia. Now, I didn't pick that out of the sky. That's either in Henschke's or Sone's article.

Now, what is that? Is that cancer? Sone includes it as a cancer. I don't think adenomatous hyperplasia is a cancer. He includes it in cancer.

That's going to end up with an open lung removal for what I think is noncancer. Now, you take this out of a trial, take it out of a trial, and everything gets worse because trials have the greatest controls.

So now, make this general policy, we will do helical CAT scans on everybody with no data on whether it changes mortality, I will just tell you on the basis of my own experience that, once you get to general use, one of the things we all have to worry about in urging screening tests is that you move from the trial to the screen -- to general screening, and your adverse effects go up.

Q. And indeed, for instance, with colonoscopy, when we started doing that, we found out that

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indeed, especially in older patients, perforations became a lot more prevalent, yet we still do it; correct?

A. Half correct. Since we are now advocating a colonoscopy, your point is very well taken. The colonoscopy alternative. We can't put this in the law, but we are putting it in advice to anybody doing it; that, if you are going to do a full colonoscopy, instead of left-sided, before you do it, you inform the subject that there is in the range of a .5 percent risk of, just as you said, perforation or severe bleeding. Absolutely.

Q. Also, Doctor, I noted in your book, in both books, although I think only in one, did you give the reason, but -- and I will preface the question with your prior testimony so you don't feel -- you don't feel I'm trying to rule it out.

You recommend to everybody, including in the law, that you recommend to everybody that they quit smoking if they smoke; correct?

A. Sure.

Q. But in both these books, you recommended, if you don't quit, which is against your advice -- I so stipulate that's against your advice -- but if

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you don't quit, you should keep -- limit the amount that you smoke to fewer than ten cigarettes a day. That's in both these books; correct?

A. Yeah.

Q. And in one of them, you said and the reason for that is because, if you keep it below ten cigarettes a day, or half a pack a day, of filter variety, filter variety, that entails minimal risk of lung cancer and other cancers. That was your rationale in one of the two books; correct?

A. Did I say minimal? I really -- I'll accept that. You don't have to show it to me. I should have said "lesser." That's true. I said to people, I don't want you to smoke, but if you have to -- that's the wrong way to put it -- if you are going to smoke despite my advice, at least I'll show you a way of reducing the likelihood of complications.

I said it then, I stand by it now, though I will make one statement; that my national advisory board is upset with that. They say you shouldn't give -- that you shouldn't give them any outs. You should just say you have got to stop, period.

And as a public health expert, I shouldn't be saying, by the way, if you are not going to take

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this advice, at least I will show you how to do it safer. And they may well be right, that I should -- I have been saying that a lot less in recent years. You won't find that on the web site.

Q. With regards to the State of West Virginia, our Department of Health and Human Resources maintains data on the number of people who died of COPD and lung cancer in our state. Did you happen to take a look at that before you came?

A. No, I did not.

Q. All right. You are aware that over twelve hundred from COPD and over fifteen hundred from lung cancer are the 2000-2001 figures; is that correct?

A. I am not aware. I am now. It doesn't surprise me.

Q. And indeed, in the United States, there will be between three hundred and fifty four hundred thousand people who die of a cigarette related condition this year?

A. Those are the current figures.

Q. And the most current figures would indicate that, as to lung cancer, slightly more than half are former smokers, not current smokers; correct? The most current data?

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A. I don't know. But I would accept that. Former heavy smokers.

Q. I want to talk about the Council for Tobacco Research. And don't worry, I'm not going to do what they did in your deposition and see if you forgot, we will just move on and say you have applied to the Council for Tobacco Research for money to do research; correct?

A. Well, not in the last twenty or -- wait a minute. Well, we got the one grant for someplace between twenty and thirty thousand to see if we could find a bad toxin in cigarettes, and we did and published it.

And we applied for a study that was subsequently published in the journal of the National Cancer Institute to look at cigarettes around the world to see if, in countries where there was less cancer, lung cancer, the cigarettes contained more selenium, and they did not find that. I bet I applied to them for something else they didn't fund.

Q. My point was this, without going through each one -- you are right, you did apply for more than that.

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A. Did I?
Q. Yes. '71, '77.
A. It wouldn't surprise me. Anybody who has got research monies, I'm going to apply to them.
Q. Here is all I want to point out, Doc. You testified earlier that you had during your career some real specialization in studying funguses?
A. Yes.
Q. And one of the first things you did for CTR was to do a study that indeed identified something on the tobacco which you believe to be highly toxic, very carcinogenic, proved it out and published it; right?
A. Correct.
Q. And then when you applied to do some more studies about other things you thought were highly toxic in the cigarettes and could be removed, that would make them safer; right?
A. We didn't -- we never applied for anything to remove things.
Q. No, no, no. But the point is, when you identify the toxin, what you are looking to do is to try and get it out of the cigarette?
A. No, that wasn't our purpose.

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Q. You don't remember that that was when you wrote the application, is it flavus?

A. There was flavus.

Q. Forget it. Let's not go there. Let's just say this. My point is you identified a toxin, very carcinogenic toxin, you published on it. Then when you applied to find out other differences in cigarettes which might make them less carcinogenic, they wouldn't fund the research?

A. Oh, I see what you are saying. Because we demonstrated that toxin, and if you just take tobacco and put it under the microscope, you can find a fungus called alternaria in big, big numbers. And we were interested -- that's my field. We were interested in figuring out if part of the reason for tobacco being a carcinogen was the alternaria.

And I can't remember what the application was, but, yeah, we wanted to -- sure, we wanted to study that.

Q. Yeah. My only point is, though, after you published on that, finding that toxin, then they wouldn't fund any more research by you to do comparative studies of cigarettes in, like, Mexico,

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Argentina and some other places. They didn't fund that research, did they?

A. Oh, no. You mean, you think they might have been annoyed that we found strong, bad things, you might be right. That crossed my mind.

Q. And lastly, I want to look at two things that you have written; okay?

A. Sure.

Q. And be sure.

MR. SEGAL: First, Ms. Gina, if we could show the book chapter, this is Stay Well, Page 36, and let me -- and in the section "Lung," it says:

This is one cancer we know a great deal about, but it wasn't always that way.

And at the end of that paragraph you say:

By 1960, the causal relationship --

That word, "causal," is your word, not my word; correct?

A. Sure. It's correct as written.

Q. By 1960, the causal relationship had been documented beyond a reasonable doubt.

A. Absolutely.

Q. Those are your words?

A. Yeah, and they are correct.

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Q. All right. Now, in 1966, when you wrote that grant to the CTR -- let me show him his signature so he knows that --

MR. SEGAL: May I approach, Your Honor?

THE COURT: Yeah.

BY MR. SEGAL:

Q. Is that your grant application bearing your signature?

A. I have no idea. This is 1966.

Q. Look at the signature page.

A. No. I'm not going to argue with you. It looks like a good one for me.

Q. All right. If you could put up the first page of that and blow up the first paragraph. It says in 1966:

The relation of tobacco to lung carcinoma remains unsettled.

Did I read that correctly?

A. You did.

MR. SEGAL: I don't have any further questions, Your Honor.

THE COURT: All right. Redirect examination?

MR. WOODSIDE: Your Honor, I have no questions.

THE COURT: All right. May this witness now be

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excused not subject to recall?
MR. WOODSIDE: From our standpoint, he may.
MR. SEGAL: He may, Your Honor.
THE COURT: Doctor, thank you very much, sir. You may be excused.
THE COURT: All right. What do we have next?
MR. FURR: Your Honor, at this time we would like to move the admission of some additional documents, but we do not intend to publish them at this time.
THE COURT: All right. Do you want to do that now?
MS. FORBES: Yes, Your Honor.
THE COURT: All right.
MS. FORBES: Defendants move the following into evidence: RJR 5955, RJR 7131, RJR 8635, RJR 8650, RJR 8652, RJR 8672, RJR 8707, Lorillard 10808, Lorillard 11912, RJR 26589, RJR 8298, RJR 07208, PMBL 00505, PMBL 00663, PMBL 01565, PMBL 22330, and finally RJR 26739.
THE COURT: All right. Is there any further comment you wish to make to admissibility of those exhibits?
MR. BAKER: There is not, Your Honor.

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MR. WOODSIDE: Your Honor, I have one exhibit, move the admission of Defendant's DX 37122, which I may approach Ms. Miller.

THE COURT: All right.

MR. WOODSIDE: I don't believe there is any objection.

MR. BAKER: There is not, Your Honor.

THE COURT: All of those exhibits will be admitted into evidence and made a part of the record in this proceeding. Even though they are not being published to the jury at this time, they will be available to the jury during their deliberations.

MS. FORBES: That's correct, Your Honor. These are documents that have been used in our case.

THE COURT: Fine.

(The exhibits are so admitted.)

THE COURT: All right, Mr. Baker?

MR. BAKER: At this time we also would like to move some additional documents.

THE COURT: Let me finish up with one side, and then we will come back.

Anything further -- any further testimony, any further exhibits?

MR. FURR: Your Honor, ladies and gentlemen, at

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this time, the defendants rest.
THE COURT: All right. Thank you.
THE COURT: Any rebuttal?
MR. SEGAL: Plaintiffs have no rebuttal case, Your Honor.
THE COURT: Now, Mr. Baker, are there other exhibits that you are offering? Are you going to publish these?
MR. BAKER: No. These were used in our cross-examination.
THE COURT: You are formally admitting them now?
MR. BAKER: Yes, Your Honor. These would be JW-2, NM 44954, NM 44971, NM 45062, NM 45061, JDD 002, NM 45071, NM 41550, RJR 26383 A, NM 22898, NM 45604, CL1 and CL2.
THE COURT: Any further comment you wish to make in regard to the admissibility of those?
MS. FORBES: Other than what's been preserved Your Honor.
THE COURT: All right. Those are certainly on the record. All of those exhibits will be admitted into evidence and made a part of the record in this proceeding, and they are not being published now.

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They may have been used during the course of the trial, but they will be available to the jury during their deliberations

(The exhibits are so admitted.)

MR. BAKER: May I present these to Ms. Miller?

MR. SEGAL: Your Honor, may Mr. Furr and I approach real briefly?

(At sidebar:)

MR. SEGAL: I don't want to hold the jury up. I would like to make sure that the record is preserved that the documents --

THE NOTARY: I'm sorry, Scott, can you --

THE COURT: This is what I intend to do.

MR. SEGAL: I'm not going to use those words again. You know what I'm talking about.

MR. FURR: I didn't hear them. I don't know.

MR. SEGAL: All I want to say is I want to argue that's been opened. I should be allowed to rebut on it and just reaffirm the Court's ruling no, you may not use those so no one can say, well, you should have argued it again as a rebuttal case. But I didn't want to hold everybody up to make that point. But they have to be excused for you to hear that.

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THE COURT: What I'm going to do this is ask the jury to go back to the jury room for a few minutes to make sure that I can get everything in order as to whether we should have them report back so we are all in agreement on that.

And then I'm going to excuse them. So if there is anything else you want to put on such as what you just said, that's the time to do it.

MR. FURR: Okay.

MR. SEGAL: Right.

(In open court:)

THE COURT: Ladies and gentlemen, it appears that all of the evidence in this case has now been submitted. As I have indicated to you, the next phase of this trial will be to give you the law, which is called the Judge's charge to the jury.

As to when that will be and when we will hear the closing arguments, I want to just go over for a few minutes with the attorneys. So if you would go back to the jury room now, I mean, it will only be for another five or ten minutes.

Then I will assure you you will be excused for the rest of the day because I know you have other things. But I need to know, get a feel for when to

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have you return; all right?

(In open court without a jury present:)

THE COURT: All right. Mr. Segal, in regard to the last comment that you made, it was a little bit blurred on the record. So if you could repeat it so you can preserve it for the record, that would be fine.

MR. SEGAL: Yes, Your Honor. Your Honor, it would have been the intention of the plaintiffs to argue that the defendants' defense and evidence in this case opened the door with regards to the issues of compensation and the documents relating to youth, and who they designed cigarettes for, and their target of how they wanted those young people, and what age groups they need to get to start smoking in order to -- well, the Court has ruled on the documents.

My point is our argument we have reopened the door as to that and, assuming that the Court would say they have not and you may not, we then have no rebuttal case to present.

THE COURT: So in other words, what you are saying is that the rebuttal would be in those two areas if you were permitted?

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MR. SEGAL: And specifically the rebuttal would be those documents which Your Honor has already ruled on, not extrinsic documents or other documents. So that the record of your rulings and everything is clear, and I wouldn't go outside that. That's the evidence that I would try and make.

THE COURT: I understand. Does anyone want to make any further comment?

MR. FURR: Your Honor, we just stand on the record.

THE COURT: All right. In essence, the request to put on rebuttal testimony in the form of exhibits that have already been ruled upon in terms of excluding them, that ruling will remain for the reasons that I previously stated, and your objection is preserved to that ruling.

All right. Now, let's go off the record and -- because we are -- I just want to see where we are going.

(Informal discussion held off the record.)

(In open court with a jury present.)

THE COURT: Be seated, please.

All right. The general outline of what we

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discussed yesterday appears that that's what we will be doing. We will be going over matters of law this afternoon and tomorrow, and we will then put together the documents to be given to you called the Judge's charge to the jury.

I will give that to you at 8:30 on Monday morning. After that, you will hear the closing arguments of the attorneys. That may take -- I'm not saying -- I put no time period on the closing arguments. So it's limited only by what somebody feels they need, certainly, to say.

But it may take most of the day. Let's just assume that. So that it looks like we will begin the deliberation either sometime Monday afternoon or certainly no later than Tuesday morning at 8:30

So for your purposes, you are excused now. We will see you back here on -- the reason we are not doing it Friday is, Friday has always been an off day, and I have other things up in Brooke and Hancock County.

They have forgotten that I'm up there. They really don't know what I look like. We have to send up some pictures. I really have to go up there on Friday.

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That's the reason why we are not coming back here Friday. I will see you Monday morning at 8:30. Again, don't discuss the case among yourselves, don't permit anybody to discuss it with you.

We are now reaching the final days so don't read about it or watch it or do anything. Don't even think about it. And see you back here Monday morning at 8:30. Thank you very much.

(In open court without a jury present:)

THE COURT: Be seated, please. Is that everybody?

THE DEPUTY SHERIFF: That's everyone's, Judge.

THE COURT: All right. Now, all the evidence is in. Mr. Rodes, do you have any motions?

MR. RODES: Yes, Your Honor. I have a motion loosely styled for a directed verdict.

THE COURT: Well, we don't call it that any more.

MR. RODES: That's why I called it loosely styled. That's just the title.

THE COURT: It's called "judgment as a matter of law," but it's still the same thing.

MR. RODES: Well, Your Honor, we are not moving

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for judgment as a matter of law. We are moving for determination by the Court of certain issues.

THE COURT: And I think that's still judgment as a matter of law on certain issues. I think we are talking about the same thing.

MR. RODES: There you go.

THE COURT: In other words, what we have is we have a -- basically we have seven issues in this case, six as outlined in Bower and the seventh being the -- what we will call generically the conduct or the standards set forth in Mayer v. Frobe. That's what we have.

And what you are asking for is a determination on some of those issues.

MR. RODES: Yes, Your Honor. Four of them.

Your Honor, should I also hand up the points for charge at this point?

THE COURT: Any time.

MR. RODES: If I may approach?

THE COURT: I will be happy to have it. I'm not going to look at it now, but -- thank you.

Which of the four elements of Bower are you moving?

MR. RODES: Elements 1, 2 and 6 and part of 3,

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which actually is the product defect theory, which is only one of several theories we have advanced under tortious conduct.

THE COURT: All right. I always want to hear your eloquence, Mr. Rodes, but let me just tell you what's been on my mind, and then you can respond to it. Or maybe I will give you my thoughts, which have not been truly crystallized yet, but these are things that are on my mind.

MR. RODES: All right.

THE COURT: In terms of taking the various parts of this case, considering it to be a seven-part case, and as to which of those parts, or all, are susceptible to jury consideration.

You agree with me, don't you, Mr. Rodes, that you need, in order for there to be a -- the relief sought here, even though it still may be amorphous, I appreciate, that but in order for the plaintiffs to recover, all elements of Bower have to be met?

MR. RODES: Yes, Your Honor.

THE COURT: So we start from that premise; right?

The areas of concern that I have that I am -- and this goes to both sides now when I make these

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1 comments. Based on all that I have heard, Elements
2 1, 2 and even 3 and 4, I have a hard time seeing
3 what the jury issues are on those issues. I
4 certainly see 5 and 6 as being and also the conduct
5 ground, 7, as being jury issues.
6 And this is what bothers me, and I'm taking the
7 testimony of the defendants' witnesses. If you
8 really -- I hear what they are saying is -- and I
9 will give you a chance to maul over this, so maybe
10 you can come back after lunch. And it just -- it
11 gives me great pause.
12 But I have a hard time understanding why a
13 cigarette as manufactured, that's been the subject
14 of many days of testimony, is not an inherently
15 dangerous product under Ryland v. Fletcher ,and I
16 keep coming back to that.
17 I keep come going back and forth because, even
18 if you make it as safe as you can, it's still
19 unsafe, which is really the essence of Ryland v.
20 Fletcher.
21 That is a big reach in our jurisprudence in
22 West Virginia. Justice Miller in Morningstar was
23 quick to say that we are not, at least in 1979,
24 incorporating what is referred to as the Ryland v.

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1 Fletcher doctrine, or inherently dangerous product
2 into our product liability jurisprudence, because,
3 in using Justice Miller's term, and he's quoting
4 Prosser on torts, that secondary, but we all know
5 Prosser is not too bad, but he's -- you know, he's
6 written some good stuff.
7 In the ordinary product liability case, the
8 product, if safely made, is not dangerous, but
9 becomes so only by virtue of a defect. And as I
10 hear the testimony, primarily of the defendants'
11 witnesses, is that, no matter what we do, we can't
12 make it a safe product.
13 And that came out in many ways when we were
14 talking about the Eclipse, Premier, Advance, and
15 then there was one other, I thought.
16 MR. FURR: Accord.
17 THE COURT: Yeah. Is it -- are you going to
18 say it's a safe product? No, we are not going to.
19 We are going to say it may be safer and use that
20 kind of conjugation of the word.
21 But this is what bothers me. No matter what
22 you do, no matter what precautions you take, that
23 you don't really need to rely upon negligence or
24 defective product because you can't make it safe as

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of right now.

So somebody is going to have to tell me why that is not an inherently dangerous product, which really just translates, insofar as this jury is concerned, is don't -- I wouldn't suggest telling them that, so you understand all my thinking, is that simply that it's just tortious conduct, which is really what the element is in No. 3.

In other words, not to tell this jury that a cigarette is inherently dangerous. I don't think that's necessary under Bower.

But what bothers me is -- and I don't think, again, based upon the testimony of the defendants, that there is no question that a person who smokes a cigarette has been exposed to a proven hazard -- it is, by their own words, as I see it -- to tortious conduct, that is an inherently dangerous product.

And No. 4 is a little bit -- maybe is not as clear to me -- and if it's not clear, it's going to the jury -- as to whether or not, because of that exposure, there is an increased risk of contracting a serious latent disease.

I mean, even when I hear this last witness, I mean, that man is -- this Dr. Louria, he came to

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tell a story, and it was impressive. It is. The man devoted his life to preventive medicine, and I think he concedes that; that there is exposure to increased risk of contracting serious latent disease.

Where this case really is, really the gut issues in this case, are in Items 5 and 6, and then the pendulum swings the other way. I mean, it's still a factual issue, but some of the testimony in regard to 5 and 6 is very impressive as far as advanced by the defendants.

But I still think that they are factual issues. And certainly 7, the conduct ground is clearly a factual issue.

So that's what's on my mind. And I will be happy to hear you. I mean, I really need to hear both of you.

MR. RODES: Your Honor, one small point, if I missed something by not moving for directed verdict on Item 4, I would like to move for that orally.

THE COURT: Or judgments as a matter of law on that point?

MR. RODES: Yes, Your Honor.

THE COURT: The way I think, I'm just putting

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1 this whole -- if in fact that is so, then I
2 believe -- and I will hear you on this also -- how
3 that would be handled is that the jury would be told
4 these are -- the issues relating to 1, 2, 3 and 4
5 have been determined as a matter of law, if I -- I'm
6 not saying I'm there. I have wrestled with this in
7 my mind for the past ten days, particularly after
8 hearing many of the defendants' witnesses and trying
9 to take what I have heard and fit it into Ryland v.
10 Fletcher. And I have a hard time coming to any
11 other conclusion, so help me.
12 I mean, the easiest thing to do, the easiest
13 thing to do in this case from a judge's standpoint
14 is to say, here, we have got fine folks here, they
15 have heard it all, let them just hear the whole
16 thing, let them make those findings.
17 And the other side of that is is that because
18 we are talking about an integrated set of standards,
19 if we direct as a matter of law on one, what does it
20 do to the others? I'm concerned about that.
21 So there. Now, go have a good lunch, and
22 that's what's on my mind. And I will be happy to
23 hear you back here at 1:00 on that, and any help you
24 can give me, I would deeply appreciate.

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MR. WAJERT: Your Honor, if I might just briefly, I have -- if I could approach, we have our proposed jury instructions and verdict form and a simple one-page motion which renews our Rule 50 motions.

THE COURT: That would be fine. Surely I will have it.

What about a verdict form, Mr. Rodes?

MR. RODES: It's attached.

THE COURT: Is that part of the package?

MR. RODES: Yes.

THE COURT: All right. That's good. Thank you.

MR. WAJERT: You are welcome.

THE COURT: All right. See you back here at 1:00.

MR. SEGAL: Do you want two?

THE COURT: Two what?

MR. SEGAL: Two packets?

THE COURT: Yeah, he will take another one.

MR. WAJERT: Your Honor, that's just a hard copy, but I'm having a disk brought down.

THE COURT: You talk to Doreen, she will be here. She will tell you what she needs, and she's

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easy to get along with. She knows what she's talking about.

(Thereupon, a luncheon recess is taken at 11:25 a.m.)

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